FILED ELECTRONICALLY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/549,385	Confirmation No.: 6082
Applicant	:	Thorsten Siess, et al.	
Filed	:	June 30, 2006	
Art Unit	:	3763	
Title:	:	INTRODUCTION DEVICE FOR INTRODUCING AN OBJECT INTO A VESSEL OF A BODY	
Examiner	:	Quynh-Nhu Hoang Vu	
Docket No.:	:	IMPEL.71975	
Customer No.	:	24201	November 12, 2008

Mail Stop Appeal Brief - PATENTS
Commissioner for Patents

APPEAL BRIEF

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed on August 14, 2008 and the Notice of Panel Decision from Pre-Appeal Brief of September 12, 2008. A request for a one month extension of time to November 12, 2008 along with the requisite fee is being filed herewith.

INTRODUCTION

The present invention relates to an introducer for facilitating the insertion of an intravascular device into a blood vessel. The device serves to dilate intervening tissue in order to gain full access into the interior of a vessel and then provides a passageway through which the intravascular device can be introduced. The challenge has been to limit the diameter to which the tissue is dilated in order to minimize trauma to the tissue without compromising the ability to extend an intravascular device there through.

I. REAL PARTY IN INTEREST

The real party in interest is Impella CardioSystems AG. This application was originally assigned by the inventors, Thorsten Siess and Josef Penners to Impella CardioSystems GmbH, by Assignment executed September 23, 2005 and September 26, 2005, respectively. Impella CardioSystems GmbH was subsequently restructured as Impella CardioSystems AG.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

The patent application has 8 pending claims. All pending claims were finally rejected in the final Office Action of May 14, 2008.

IV. STATUS OF AMENDMENTS

A response to the final Office Action of May 14, 2008 was filed on July 11, 2008. The response did not include an amendment of any of the claims. In the Advisory Action of July 23, 2008, the Examiner indicated that the applicants' argument was unpersuasive.

V. SUMMARY OF THE INVENTION

The present invention is directed to an introducer that has a configuration that marks a substantial departure from previously used introducers and, indeed, the introducers that are described in the cited references. The claimed introducer (FIG. 1, #10) includes a dilator (FIG. 1, #11) in combination with a tubular channel (FIG. 1, #15). The dilator element has a conical tip (FIG. 1, #14) and is retractable within the tubular channel (FIG. 2 and specification, page 3, lines 5-7). The tubular channel has an extremely small wall thickness of a maximum of 0.06 mm (specification, page 2, lines 21-21) and is formed of a hard plastic (specification, page 2, lines 16-17) such as polyamide or polyester.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

This appeal has one issue, namely whether the pending claims are unpatentable under 35 U.S.C. § 103(a) as obvious over Fischell et al. (EP 0 596 172 A2) in view of applicant's own application, Siess et al (US 2004/0044266). More particularly, the issue boils down to whether the primary reference describes or even suggests an introducer that includes an extremely thin sheath or channel formed **exclusively** of plastic in combination with a retractable dilator. The applicants maintain that the Examiner mischaracterizes the structure and interrelationship of the various components of the cited reference in a strained and unreasonable effort to find the present invention therein.

VII. ARGUMENT

The rejected claims all require the introducer device to include a retractable dilator in combination with a channel that is in effect readily deformable. The channel is claimed in terms of a **structure** that is readily deformable, i.e. it is claimed in terms of its composition and thickness - "formed exclusively of hard plastic" with a wall thickness of "not larger than 0.06 mm." Such limitations were selected as they necessarily render an introducer sheath having such properties to be readily deformable and effectively serve to distinguish the prior art. Moreover, it avoids any confusion that could otherwise arise in attempting to quantify the "readily deformable" function of the present invention versus a "**non**-kinking" function of the prior art including that of the cited reference.

VII. THE SHEATH OF THE PRIMARY REFERENCE IS NOT FORMED EXCLUSIVELY OF PLASTIC

In the case of the primary reference, the sheath that is described therein is a **metal** reinforced structure which is therefore clearly not formed "exclusively of plastic." More particularly, the introducer sheath (10) of the cited reference is described in the abstract of the document (Exhibit 2) as having an internal **metallic** helical coil (12) within a thin plastic covering (20). As such, the device embraces the conventional approach wherein the sheath is configured so as to **resist** deformation rather than allow deformation to readily occur, as is articulated in the reference at page 2, line 17 and even more unequivocally at page 2, line 58:

"This ratio of wire width to wire thickness is a very important consideration in the design of the sheath **in order to prevent the sheath from collapsing**." Not only does a reinforcement structure increase the overall diameter of the device but would additionally require the insertion of a dilator ("not shown" page 4, line 53) in the event the introducer does in fact become deformed.

In contrast thereto, the present invention represents a thoroughly unconventional approach in this regard as it had unexpectedly been found that the substantial axial force that was typically needed to correct any deformation of a deformation-resistant sheath was the result of the sheath's own resistance to deformation rather than the forces applied by the surrounding tissue. Accordingly, because the channel element of the present invention is readily deformable, it does not require the reinsertion of a dilator in order to apply sufficient axial force to correct any deformation as the axial force generated by the insertion of an intravascular device is sufficient.

IX. THE REINFORCEMENT COIL OF THE PRIMARY REFERENCE IS NOT A DILATOR AND IS NOT RETRACTABLE

In an effort to find the claimed structure in the sheath shown and described in the primary reference, the Examiner undertakes a hypothetical disassembly of the sheath and then refers to only its outer covering as the 'sheath' while characterizing its inner reinforcement coil as a retractable 'dilator'. This is a wholly unreasonable characterization of the structural elements as well as an unreasonable interpretation of the teachings of the reference. Both the reinforcement coil as well as its plastic covering are part and parcel of the sheath. Not only is the outer plastic covering said to be effectively fused to the underlying metal coil (such as by heat shrinking, hot dipping or over extrusion – page 3, lines 27-32) but its projections into the spaces between adjacent windings of the coil (Figs. 2A-3D) serve to mechanically lock the covering to the coil. Retraction of the reinforcement coil relative to its plastic covering is therefore effectively and positively precluded. Additionally, the proximal end of both the outer covering as well as the reinforcement coil are described as being "moulded" to the adaptor 30 that is situated at the proximal end of the device (page 4, lines 53-73). Clearly, such construction defies disassembly while the reference clearly teaches away from any notion of the reinforcement coil being

retractable from its covering. It should also be noted that the sheath (covering plus reinforcement coil) described in the reference is for use in conjunction with a dilator (page 4, line 53) that is not shown. Characterizing the covering of a reinforced introducer sheath as the introducer sheath is no more reasonable than characterizing its reinforcement coil as a dilator when the coil reinforced sheath is to be used in conjunction with a dilator.

In straining to find the claimed structure in the cited reference, the Examiner also completely ignores the teachings of the reference which clearly teach directly away from the concept of an introducer sheath that is readily deformable. Not only is the device referred to in its very title as "non-kinking", but the reliance on the reinforcement coil to prevent the collapse of the sheath is specifically mentioned throughout the specification. The metal reinforcement coil is therefore very much a integral component of the sheath and as such teaches away from a deformable channel, let alone one that is formed exclusively of a thin plastic.

While the secondary reference (Exhibit 3) is relied upon by the Examiner for its disclosure of a dilator with a conical tip, the reference similarly relies on a conventional rigid tubing (page 2, paragraph 35, line 3) as the conduit through which an intravascular is introduced and as such suffers from the same shortcomings that are inherent in the sheath of the primary reference. Moreover, it comprises the type of device that is described in the second paragraph of the present application and is precisely the type of device the claimed invention improves upon.

In sum, neither reference recognizes that a readily deformable channel in combination with a retractable dilator can provide the benefit of minimizing the overall cross section while nonetheless facilitating the insertion of an intravascular device therethrough. The cited references neither suggest such an approach nor describe a structure that can reasonably be interpreted as having the claimed elements.

X. CLAIMS APPENDIX

See Exhibit 1.

XI. EVIDENCE APPENDIX

None.

XII. RELATED PROCEEDINGS APPENDIX

None.

XIII. CONCLUSION

For the foregoing reasons, it is submitted that the present invention as claimed is not obvious over the cited references and that the Examiner's rejection of claims 1-8 was therefore erroneous. Appellant respectfully requests reversal of the rejection of claims 1-8.

Respectfully submitted,

FULWIDER PATTON LLP

/Gunther O. Hanke/
Gunther O. Hanke, Reg. No. 32,989

GOH:lm

LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
1	Appealed Claims
2	Fischell et al. (EP 0 596 172 A2)
3	Siess et al. (US 2004/0044266 A1)

EXHIBIT 1

EXHIBIT 1

CLAIMS ON APPEAL:

1. An introduction device for introducing an object into a vessel of a body, comprising:

a tubular channel and a dilator carrying the channel, wherein the dilator comprises a conical tip portion and is adapted to be retracted from the channel, wherein the channel has a wall thickness not larger than 0.06 mm and is formed exclusively of a hard plastic material.

2. The introduction device according to claim 1, wherein the inner diameter (D1) of the channel is at least as large as the outer diameter (D2) of the dilator prior to sliding the channel onto the dilator.

3. The introduction device according to claim 2, wherein the channel forms a force fit on the dilator.

4. The introduction device according to claim 1, wherein the dilator and/or the channel comprise a low-friction slip material.

5. The introduction device according to claim 1, further comprising a connecting device for injecting a pressurized fluid into the channel.

6. The introduction device, according to claim 1, wherein the channel comprises a distal end section which at least partly overlaps the conical tip portion.

7. The introduction device according to claim 6, wherein the end section is defined by a tear-off line.

8. The introduction device according to claim 1, wherein the end section of the channel is adhesively bonded to the tip portion of the dilator.

EXHIBIT 2

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 596 172 A2**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **92311736.0**

(51) Int. Cl.5: **A61M 25/01**

(22) Date of filing: **23.12.92**

A request for correction of table 1 of the description and claim 1 has been filed pursuant to Rule 88 EPC. A decision on the request will be taken during the proceedings before the Examining Division (Guidelines for Examination in the EPO, A-V, 2.2).

(30) Priority: **03.11.92 US 965961**

(43) Date of publication of application:
11.05.94 Bulletin 94/19

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE

(71) Applicant: **Fischell, Robert E.**
14600 Viburnum Drive
Dayton, Maryland 21036(US)
Applicant: **Fischell, Tim A.**
1018 Chancery South
Nashville, Tennessee 37205(US)

(72) Inventor: **Fischell, Robert E.**
14600 Viburnum Drive
Dayton, Maryland 21036(US)
Inventor: **Fischell, Tim A.**
1018 Chancery South
Nashville, Tennessee 37205(US)

(74) Representative: **Lambert, Hugh Richmond**
D. YOUNG & CO.,
21 New Fetter Lane
London EC4A 1DA (GB)

(54) Radiopaque non-kinking thin-walled introducer sheath.

(57) A non-kinking introducer sheath (10) for introducing and guiding catheters into an artery or other similar vessel in the body is described. The sheath comprises an internal helical metal coil (12) fabricated from flat wire, and located within a thin plastic covering (20).

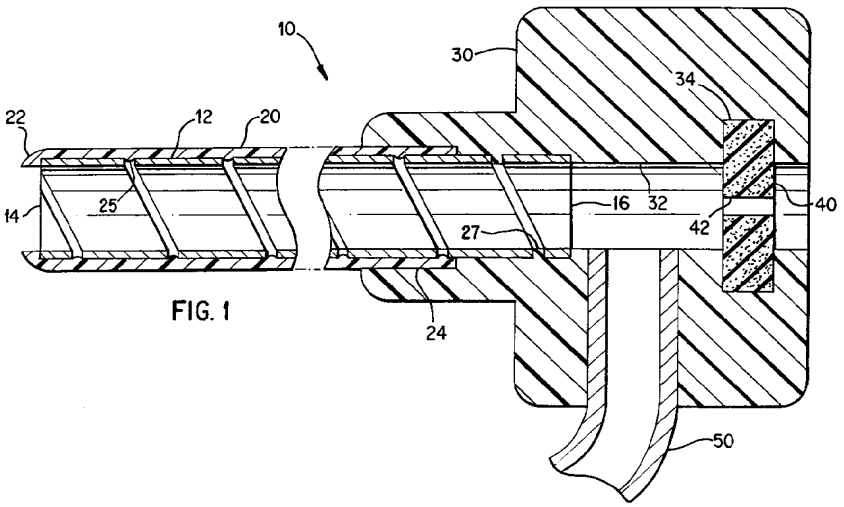


FIG. 1

EP 0 596 172 A2

This invention relates to introducer sheaths that are inserted through the skin into an artery or other vessel in a living body for the purpose of subsequent percutaneous insertion and guidance of a transluminal catheter.

It is common practice in the fields of angioplasty and atherectomy to insert catheters into the artery through a plastic sheath. These sheaths are typically made from PVC or an equivalent plastic and typically have a wall thickness of 0.254mm (10 mils) it being highly advantageous to have those sheaths as thin-walled as possible. The inner diameter of such sheaths is determined by the diameter of the catheter to be placed through it, so that in order to provide that 0.254mm thickness the external diameter of the sheath is typically 0.508mm (20 mils) greater than the inside diameter. However, it would be highly advantageous to reduce the outside diameter of the sheath so as to minimise arterial distention, thereby reducing the bleeding that occurs at the insertion side after the catheter and sheath are removed from the artery, but against that significant problems do arise from the tendency of extremely thin-walled sheaths to kink or bend at the point of entry into, for example, the femoral artery or where they pass through a highly curved section of an iliac artery. Also because they are made from plastics materials, the current thin-walled sheaths are not significantly radiopaque.

The present invention to eliminate the shortcomings of the prior art devices in order to provide a radiopaque sheath that is non-kinking and with a thinner wall as compared with sheaths that are currently available. This is achieved by inserting into the sheath a helical metal coil preferably fabricated from flat wire or by utilising as the sheath such a helical metal coil covered or coated with a thin plastic covering. This may be provided by means of a plastic material coated onto and between the turns of the metal coil or by using a length of heat shrinkable tubing, or by moulding or extruding plastic over the thin helical metal coil. At the proximal end of the sheath is an adapter (hemostasis valve) through which the catheter may subsequently be placed. This adapter would typically be moulded from a plastic so as to both join onto the metal coil as well as mould onto the plastic covering of the metal coil. At its distal end, the sheath would advantageously combine a metal portion for radiopacity and at its extreme end a soft plastic tapered end piece.

The invention will be further described by reference to the accompanying drawings, in which:

Fig. 1 is a cross-sectional view of a non-kinking, thin-walled sheath according to this invention and comprising single helical metal coil having a plastics covering and with plastic extensions between adjacent turns.

Fig. 2A shows a wall section of the sheath with a plastic extension incompletely filling the space between adjacent turns.

Fig. 2B shows a wall section of a sheath where the spaces between the adjacent turns of the coil are completed filled.

Fig. 2C shows a wall section of a sheath where the spaces between the adjacent turns of the coil are almost filled.

Fig. 3A shows a wall section of a sheath wherein the flat wire has rounded ends and is considerably thinner than the plastic covering and there is a greater spacing between adjacent turns.

Fig. 3B shows a wall section of a sheath wherein there is an extension of the plastic covering between adjacent turns even though the adjacent turns are touching and the flat wire is chamfered on all corners.

Fig. 3C shows a wall section of a sheath wherein only the inner corners of the flat wire metal coil are rounded.

Fig. 3D shows a wall section of a sheath wherein only the inner corners of the flat wire metal coil are chamfered.

Fig. 3 is a longitudinal cross section of the distal end of the sheath illustrating a metal tip.

Fig. 4 is a longitudinal cross section of the distal end of the sheath illustrating a metal tip.

Fig. 5 is a longitudinal cross section of the distal ends of the sheath illustrating a metal insert near the sheath's distal end and a soft plastic tip and a very thin-walled, interior tube having lubricious coating on its interior surface.

Fig. 6 is a cross-sectional view of the distal end of a non-kinking sheath which has two helical metal coils with a plastic extension into the space between adjacent turns of the outer coil.

Referring first to Fig. 1, a non-kinking, thin-walled sheath 10 is shown with an inner metal coil 12 that lies within a plastic covering 20 for most of the length of the sheath with a plastic adapter 30 moulded onto the proximal end of the sheath 10. The metal coil 12 would typically be fabricated from flat stainless steel wire or an equivalent springy metal. Metals such as 300 or 400 series stainless steel, nickel alloys such as Monel metal, or Inconel or beryllium copper, tantalum or gold alloys could be used for the flat wire metal helix material. The thickness of the wire would typically be in the range 0.0254 to 0.127mm (1 and 5 mils) and the width of the wire would typically be between 3 to 80 times the wire thickness. This ratio of wire

width to wire thickness is a very important consideration in the design of the sheath in order to prevent the sheath from collapsing while still providing a very thin wall. By actually building a model of this sheath, it has been determined that for the most desirable wire thicknesses which provide a very thin wall while preventing the sheath from collapsing in normal handling, only certain ranges of wire width to wire thickness are reasonable and these ratios are presented in Table 1. This table clearly shows greater width-to-thickness ratios are required as the wire thickness is decreased.

Table 1

Acceptable Wire Width-To-Thickness Ratios As a Function of Wire Thickness	
THICKNESS RANGE mm(mils)	**WIDTH-TO-THICKNESS RATIO**
0.0635 to 0.0880 (2.50 to 3.50)	3 : 20
0.0381 to 0.0632 (1.50 to 2.49)	5 : 50
0.0190 to 0.0378 (0.75 to 1.49)	12 : 80

The flat wire helix would typically be wound on a mandrel in a similar manner to the way that spring wire guides are made at the present time. Another method to form the flat wire helix would be by using machines than form tension or compression coil springs. The inner diameter of the helical coil would typically lie in the range 1.016 to 5.08mm to 200 mils) depending on the size of the catheter that has to be inserted through it. The distal end 14 and the proximal end 16 of the coil 12 would be typically cut off square as shown in Fig. 1.

Covering the helical coil 12 would be a plastic covering 20 having a thickness in the 0.0254 to 0.203mm range (1 to 8 mils) and which would typically be made from polyethylene, polyurethane, PVC, Surlyn or a similar plastic material. One method for forming the covering 20 so that it fits tightly around the helical coil 12 would be by sliding the coil 12 through a tube of the plastic and then heat shrinking the plastic onto the helical coil 12. Another method would be to dip coat the coil 12 into a liquid plastic material that hardens onto the helical coil 12 after dipping. Another method would be to overextrude plastic over the coil 12. A polytetrafluoroethylene (Teflon: Registered Trade Mark) mandrel could be inserted inside the metal coil 12 before dip coating or overextruding. Whatever method is used to form the plastic covering 20, the plastic material could have a partially filled extension 25 or a fully filled extension 27 each of which projects into the space between adjacent turns thereby preventing unwanted longitudinal displacement of one turn relative to another when the sheath 10 is severely bent. The inside diameter of either extension 25 or 27 is smaller than the outside diameter of the metal coil 12 and larger than or equal to the inside diameter of the metal coil 12.

Figs. 2A, 2B, 2C and 2D show four sheath wall sections having four different types of plastic extensions that keep adjacent turns of coils separated from each other.

Fig. 2A is an enlarged view of the wall section of the sheath shown in Fig. 1 which has a partially filled extension 25 protruding from the plastic covering 20 which extension only slightly fills the space between adjacent turns. However, the sharp corners of the metal coil 12 prevents unwanted longitudinal displacement of the turns of the coil when the sheath is bent. This form of plastic extension is typical of that which would be obtained with heat shrinkable tubing followed by centreless grinding of the outer surface of the covering 20.

Fig. 2B shows a completely filled extension 27 of the plastic covering 20 which design is also shown in Fig. 1. This shape would typically be obtained when the plastic covering 20 is overextruded with a right fitting cylindrical mandrel (typically made from a polytetrafluoroethylene cylinder) placed inside the metal coil 12. The tight fitting mandrel (not shown) prevents plastic from adhering to the inner surface of the metal which, if it should occur, would result in an undesired increased wall thickness of the sheath. This type of projection could also be obtained by placing a liquid plastic material between the turns of a metal coil that has been wound on a mandrel and then placing an outer plastic covering 20 over the metal coil 12. An importance of this design is that the sharp inner corners of the flat are covered.

Fig. 2C shows a mostly filled extension 26 which could be formed by placing a hollow polytetrafluoroethylene (Teflon) tube (not shown) inside the metal coil and then inflating the tube and then overextruding the plastic covering 20 onto and in between the coil 12. The tube would be deflated to allow it to be withdrawn. An importance of this design (like Fig. 2B) is that the sharp inner corners of this flat wire are covered.

Fig. 2D shows an over-filled extension 28 which could be formed by using heat shrinkable tubing for the plastic covering 20 and then heating the metal coil 12 until the metal coils "melt" into that plastic covering 20. It is also possible to overextrude the plastic covering 20 and with the appropriate type of plastic, pressure and temperature to form the plastic shape as shown in Fig. 2D. This design covers the inner corners of the flat wire and furthermore, an inner lubricity coating could be applied to the plastic to allow easier passage for an inserted catheter.

Figs. 3A, 3B, 3C and 3D illustrate four other embodiments of wall sections for a non-kinking sheath. Fig. 3A shows an embodiment in which the flat wire metal coil 33 has a wire thickness that is considerably smaller than the thickness of the plastic covering 20. Furthermore, the coils 33 have inner and outer rounded edges. This particular wall section is shown with a plastic extension 27 similar to that shown in Fig. 2B. The width of each turn of the coil 33 is L1, and the length of the separation between turns is L2. In Fig. 3A, L2 is greater than L1. Typically L2 would be equal to or less than L1. However, if greater flexibility is desired, L2 can be several times greater than L1. However, if L2 is greater than 1 to 2 cm, then the sheath might no longer be non-kinking. It should also be understood that a sheath might use a variable spacing L2 between adjacent turns. For example, L2 might be 0.5mm for most of the sheath's length but L2 might be gradually increased to 5mm at the sheath's distal end in order to increase the flexibility of the sheath's distal end.

Fig. 3B shows a wall construction in which adjacent turns are touching. However, the ends of the coils 35 are shaped so that a plastic extension 29 of the plastic covering 20 extends into the space between adjacent touching turns.

Figs. 3C and 3D show an embodiment of the coils 37 and 39 in which there is a generally squared off outer corner at the end of each turn and a generally rounded inner corner at the end of each turn. Specifically, in Fig. 3C the inner corners of the coil 37 are rounded and in Fig. 3D the inner corners of the turn 39 are chamfered. It should also be understood that the outer surface of the coil could be finished so as to prevent adhesion of the plastic covering 20 to the coil; or conversely, the outer surface of the coil could be treated to cause the metal coil to bond to the plastic covering 20. Generally, adhesion or bonding of the coils outer surface to the plastic covering 20 will result in a less flexible sheath. Furthermore, increasing the ratio of L2/L1 (as seen in Fig. 3A) will increase sheath flexibility. It is well known in the wire forming art that any of the wire shapes showing in Fig. 3 could be obtained by slitting, drawing or extruding the flat wire through a die; or a combination of these methods could be used to form the desired cross section of the generally flat wire. The cross section of Fig. 3A could also be obtained by rolling down round wire.

The shapes shown in Figs. 3C and 3D are advantageous in that their sharp outside corners dig into the plastic covering 20 thus preventing unwanted longitudinal displacement of the turns of the coil when the sheath is severely bent. Furthermore, the rounding or chamfering of the inside edge prevents the outer surface of a tight fitting catheter from being damaged by exposed sharp inner corners such as those shown in Fig. 2A as a tight fitting catheter is pushed through the sheath. Also, a tight fitting catheter would slide through the inside of the sheath with less friction or catching (especially through bends in the sheath) if the inside corners of the metal coil are rounded or chamfered as shown in Figs. 3C and 3D.

It also envisioned that any of the flat wire metal coil designs described herein could be coated with a metal or plastic so as to enhance the sheath's radiopacity or to decrease frictional forces on any catheter that would be placed through the sheath. For example, gold or tantalum plating of the flat wire would enhance the sheath's radiopacity. Furthermore, the metal coil could have a lubricity coating applied to decrease frictional forces of objects passing the sheath's interior lumen. Additionally, the bare metal could be given a thin plastic coating which would then have a lubricity coating applied. Further, there could be a very thin, separate plastic cylinder inside the metal coil. Further, as to coatings, a lubricity coating could be applied to the sheath's exterior plastic covering 20 to allow the sheath to enter human tissue and advance through human blood vessels while minimising frictional resistance. The outer surface of the plastic covering 20 could also be treated with an anti-bacterial coating which would be especially important for sheaths that remain in a vessel for more than a few hours. Still further, the exterior plastic covering 20 could be centreless ground to make a smoother outer surface of the sheath.

In Fig. 1 we see that the distal tip 22 of the plastic covering 20 might be heat moulded to an appropriate shape which can readily pass through the arterial wall with the aid of a dilator (not shown). The proximal end 24 of the covering 20 would have moulded onto it a plastic adapter 30 (typically including a hemostasis valve) which can have a side-port 50 as shown in Fig. 1. The adapter 30, which may be formed from the same plastic material as the covering 20 or from another material such as PVC, would also be moulded onto the proximal end of the helical coil 12. The adapter 30 would have an interior cylindrical hole 32 whose inside diameter is moulded to match the inside diameter of the helical coil 12. A cylindrical

groove 34 would be moulded into the adapter 30 so as to accept a foam rubber packing gland or hemostasis valve 40. The packing gland 40 has a hole 42 through its centre to allow for the passage of a catheter. The purpose of the gland 40 is to seal around the outside diameter of the catheter when it is in place to prevent arterial blood from escaping between the inner cylinder 32 of the adapter 30 and the outside diameter of the catheter that is percutaneously placed into the arterial system. The packing gland 40 is only indicative of more sophisticated hemostasis valves that would be used with such a sheath. An example of such a valve is shown in U.S. Patent No. 5,041,095 by P.K. Littrell entitled "Hemostasis Valve".

As previously described, the strip of metal forming the helical coil 12 would have a thickness in the range o.0254 to 0.127mm (1 to 5 mils). Similarly the plastic covering 20 would typically have a thickness in the same range to that the total thickness of the coil 12 and covering 20 would be in the range 0.0508 to 0.254mm (2 to 10 mils). At 0.254mm thickness, the sheath would have the advantage of being non-kinking and radiopaque. However, it would not have any advantage in reducing the outer diameter of the sheath 10 as compared to other sheaths that are currently available. However, as we approach wire and plastic covering thicknesses the order of 0.0508mm (2 mils), the outer diameter of the sheath 10 is significantly reduced. There is a distinct advantage in dramatically reducing the wall thickness of the sheath 10 while at the same time having improved resistance to kinking which is provided by the strength of the helical coil 12.

Fig. 4 illustrates an improved tip design for this type of thin-walled sheath 10. As typical for this sheath design, the metal coil 12 is encased in a plastic covering 20. A metal tip 60 is joined to the coil 12 and/or covering 20 by adhesive bonding, welding or brazing or an equivalent joining means. Although a stainless steel tip could be used, a dense metal such as gold or tantalum (or an alloy of these metals) would have the advantage of greater radiopacity.

Fig. 5 illustrates the distal end of a sheath 10 with a metal insert 62 joined to the coil 12 and plastic covering 20. The design of Fig. 5 would be similar to that of Fig. 4 except that a plastic tip 64 extends beyond the metal insert 62. Furthermore, the inside diameter of the insert 62 could be smaller than the inside diameter of the coil 12; and the inside diameter 66 of the plastic tip 64 could be still smaller. This design would provide a tighter fit around the dilator for improved insertion of the sheath into a vessel. Further, the soft plastic tip is potentially less damaging to the soft tissue into which the sheath plus dilator would be inserted.

Fig. 5 also shows a separate very thin-walled, plastic tube (or coating) 68 which could be placed interior to the sheath to improve lubricity. Such a tube could be advantageously made from polytetrafluoroethylene or a different plastic with an interior surface coating to improve lubricity. Such an interior tube could be used with any tip design of the sheath. Fig. 5 also shows a separate plastic spacer 69 that lies between adjacent turns of the metal coil 12 and between the inner plastic tube 68 and the outer plastic tube 20. Thus, if desired, as many as three different plastic materials can be used for elements 20, 68 and 69 in order to optimise the properties of these three different parts of the sheath.

Although Fig. 1 shows only a single coil 12, it is envisioned that the helical coil 12 might be made from two separate metal coils, one inside the other, that are wound in opposite directions (as shown in Fig. 6) so as to improve the strength of the sheath. Fig. 6 shows the distal end of a two coil sheath 11 which has an inner helical metal coil 17, an outer helical metal coil 13, both of which are finished with a straight distal end 15. Fig. 6 also shows a plastic covering 21 with a moulded distal end 23 which design is similar to Fig. 1. A Fig. 6 type design in which the inner metal coil is nominally 0.0508mm (2 mils) thick, the outer metal coil is nominally 0.0508mm (2 mils) thick and the plastic covering is also 0.0508mm (2 mils), would achieve a non-kinking sheath design which still has a significant wall thickness reduction as compared to sheaths that are currently available.

All the sheaths designs described herein have metal coils which are intrinsically radiopaque. Hence these sheath designs have the additional functional attribute of being radiopaque even without the addition of highly radiopaque distal tips.

The possibility of a very thin plastic coating or plastic tube on the interior surface of the inside metal coil is also envisioned for these sheath designs as shown in Fig. 5. Such a coating or plastic tube would optimally have a very low coefficient of friction.

Although the utilisation of sheaths in arteries is described herein in considerable detail, the sheath that is taught herein is also able to be used for access to a variety of lumens of humans or animals, such as veins, urethras, fallopian tubes, biliary ducts, bronchial tubes or any similar vessel in a living body.

Various other modifications, adaptions, and alternative designs are of course possible in light of the above teachings without departing from the scope of the appended claims.

Claims

1. An introducer sheath (10) for percutaneous insertion into a vessel of a human body and when so inserted serving as a guide for the subsequent insertion of a catheter into said vessel and having an adapter (30) including a hemostasis valve (40) located at one end of the sheath for inserting guide wires and/or catheters through the sheath and into the said vessel, characterised in that the introducer sleeve (10) comprises a wire metal coil (12) constructed from flat wire strip forming the interior wall of the sheath and coated or covered with a plastic covering (20) that is fitted onto and is in contact with the exterior surface of said metal coil.

2. An introducer sleeve according to claim 1, characterised in that the material of said plastic covering (20) projects at least partially into spaces between adjacent turns of the metal coil but without covering the interior surface of the metal coil.

3. An introducer sheath according to claim 1 or 2 characterised in that the metal coil (12) is made from stainless steel, preferably either a 300 series stainless steel or a 400 series stainless steel.

4. An introducer sheath according to claim 1, 2 or 3, characterised in that the flat wire of the metal coil has a thickness in the range 0.635 to 0.889mm (2.5 to 3.5 mils) and a width to thickness ratio to the range 3:1 to 20:1, or a thickness in the range 0.381 to 0.632mm (1.50 to 2.49 mils) and a width to thickness ratio in the range 5:1 to 20:1, or a thickness in the range 0.019 to 0.378mm (0.75 to 1.49 mils) and a width-to-thickness ratio in the range 12:1 to 80:1.

5. An introducer sheath according to any one of claims 1 to 4, characterised in that the metal coil (12) has spaces between adjacent turns that are each less than the width of a single turn of the coil.

6. An introducer according to any one of claims 1 to 4, characterised in that the metal coil (12) has spaces between adjacent turns that are larger than the width of a single turn of the coil.

7. An introducer sheath according to claim 5 or 6 characterised in that the spaces between adjacent turns are all of the same dimension.

8. An introducer sheath according to claim 5 or 6 characterised in that the spaces between adjacent turns vary in dimension along the length of the coil, the spaces between adjacent turns at the sheath's distal end preferably being greater than those at the proximal end adjacent said adapter (30).

9. A sheath according to any one of claims 1 to 4, characterised in that the helical coil (12) is formed from that metal strip having chamfered or rounded edges.

10. A sheath according to claim 9, characterised in that the chamfered or rounded edges of the wire strip in each turn are substantially contiguous with those of the adjacent turns.

11. An introducer sheath according to any one of claims 1 to 10, characterised in that the metal coil (17) is plated with a dense radiopaque metal preferably gold or tantalum.

12. An introducer sheath according to any one of claims 1 to 11, characterised in that the internal surface of the metal coil is provided with a lubricious coating.

13. An introducer sheath according to any one of the preceding claims characterised in that the outer covering of the sheath is formed by a preformed plastics sleeve, heat shrunk onto the metal coil.

14. An introducer sheath according to any one of the preceding claims characterised in that the thickness of the plastic covering is in the range 0.0254 to 0.203mm (0.001 and 0.008 inches).

15. An introducer sheath according to any one of the preceding claims characterised in that the plastic covering is centreless ground on its exterior surface to provide a smooth finish on that exterior surface.

16. An introducer sheath according to any one of the preceding claims characterised in that the plastic covering has a lubricated external surface.

17. An introducer sheath according to any one of the preceding claims characterised in that the sheath has a metal tip (60) or insert (62) at the end.

18. An introducer sheath according to claim 17, characterised in that the metal tip (60) consists of or comprises a high density radiopaque metal, preferably tantalum or gold.

19. An introducer sheath according to any one of the preceding claims, characterised in that the sheath has a thin plastics liner (68) located internally of the helical coil (12).

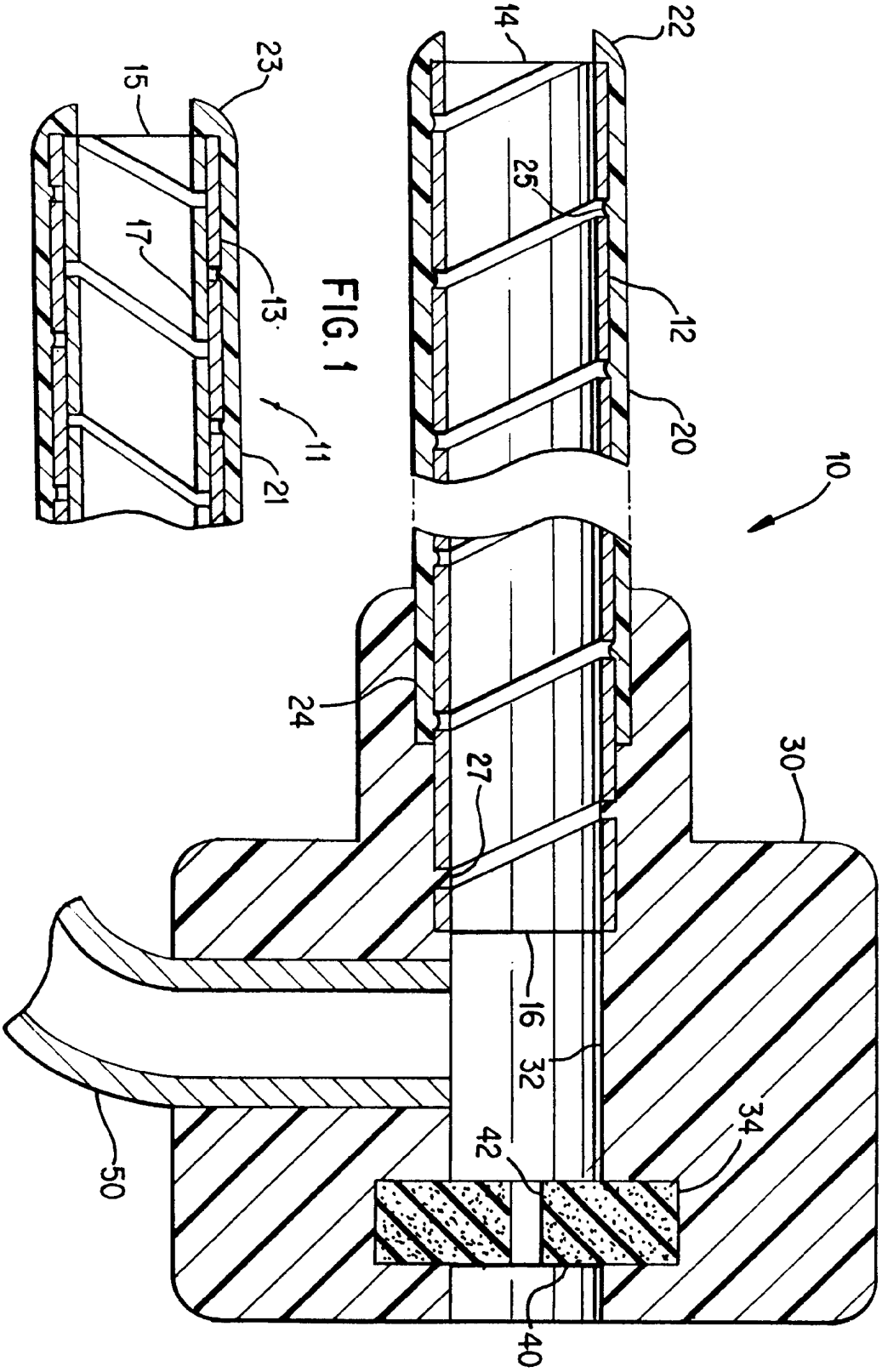
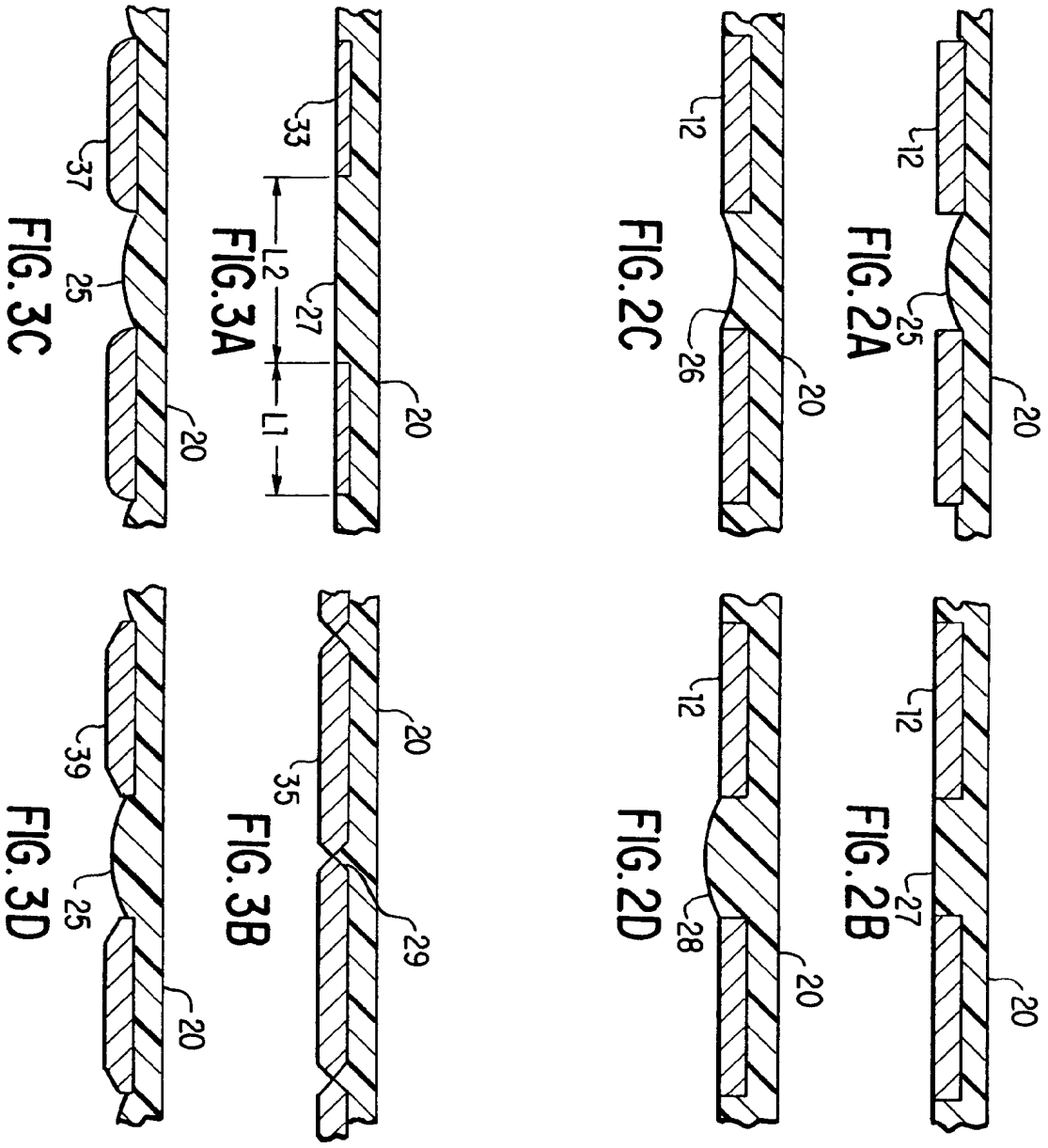


FIG. 6

FIG. 1


12
25
20
FIG. 2A
12
27
20
FIG. 2B
12
26
20
FIG. 2C
12
28
20
FIG. 2D
33
L2
27
L1
20
FIG. 3A
20
35
29
FIG. 3B
37
25
20
FIG. 3C
39
25
20
FIG. 3D

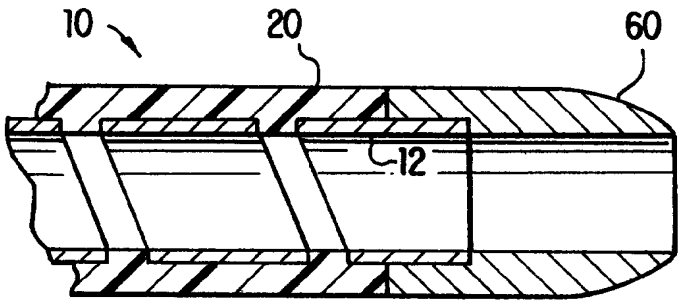


FIG. 4

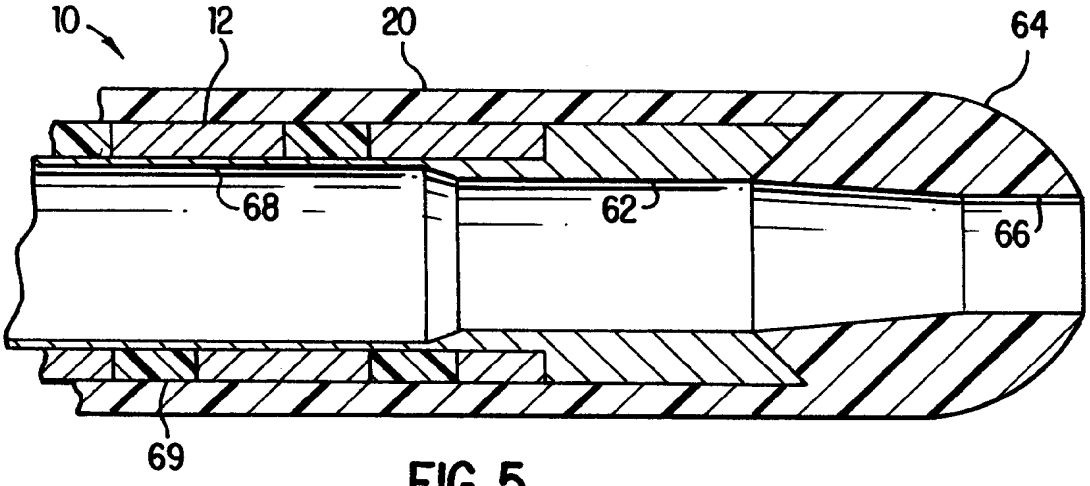


FIG. 5

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 596 172 A3**

(12) # EUROPEAN PATENT APPLICATION

(21) Application number: **92311736.0**

(22) Date of filing: **23.12.92**

(51) Int. Cl.[6]: **A61M 25/01**, A61M 25/06, A61M 39/06, A61M 25/00

(30) Priority: **03.11.92 US 965961**

(43) Date of publication of application:
11.05.94 Bulletin 94/19

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE

(88) Date of deferred publication of the search report:
15.02.95 Bulletin 95/07

(71) Applicant: **Fischell, Robert E.**
14600 Viburnum Drive
Dayton,
Maryland 21036 (US)
Applicant: **Fischell, Tim A.**
1018 Chancery South
Nashville,
Tennessee 37205 (US)

(72) Inventor: **Fischell, Robert E.**
14600 Viburnum Drive
Dayton,
Maryland 21036 (US)
Inventor: **Fischell, Tim A.**
1018 Chancery South
Nashville,
Tennessee 37205 (US)

(74) Representative: **Lambert, Hugh Richmond**
D. YOUNG & CO.,
21 New Fetter Lane
London EC4A 1DA (GB)

(54) **Radiopaque non-kinking thin-walled introducer sheath.**

(57) A non-kinking introducer sheath (10) for introducing and guiding catheters into an artery or other similar vessel in the body is described. The sheath comprises an internal helical metal coil (12) fabricated from flat wire, and located within a thin plastic covering (20).

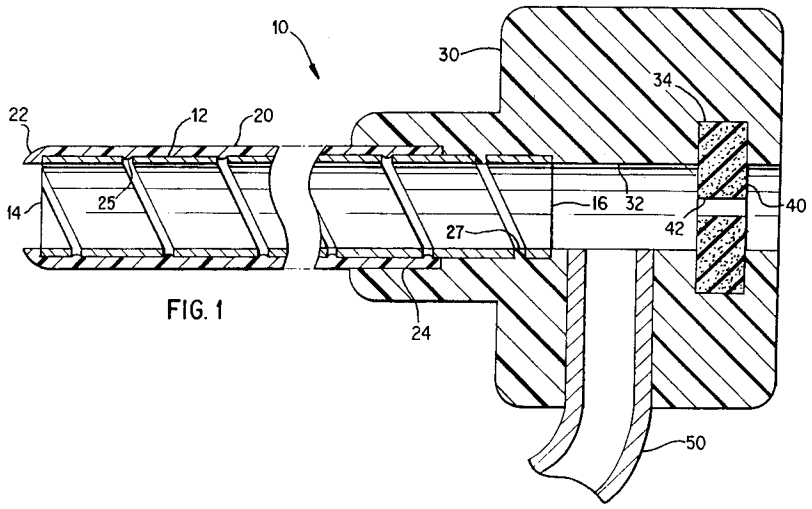


FIG. 1

EP 0 596 172 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 92 31 1736

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
E	EP-A-0 530 970 (COOK) * column 2, line 3 - column 4, line 47; figures 1,3 *	1-6,13	A61M25/01 A61M25/06 A61M39/06 A61M25/00
Y	US-A-4 634 432 (KOCAK) * column 4, line 39 - line 68; figures 1,2 *	1-7,13, 19	
Y	US-A-4 411 655 (SCHRECK) * column 3, line 48 - column 4, line 25 *	1-7,13, 19	
A	WO-A-90 02579 (MALLINCKRODT) * abstract; figure 2 *	1,12,16	
A	EP-A-0 145 489 (ADVANCED CARDIOVASCULAR SYSTEMS) * page 5, line 17 - page 6, line 5 *	1,11,17, 18	
A	US-A-5 092 848 (DECIUTIIS) * abstract * * column 7, line 16 - line 23; figure 1 *	1,17,18	TECHNICAL FIELDS SEARCHED (Int.Cl.5) A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	8 December 1994	MONNE, E

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

EXHIBIT 3

US 20040044266A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0044266 A1**

Siess et al. (43) **Pub. Date: Mar. 4, 2004**

(54) **INTRAVASCULAR PUMP**

(76) Inventors: **Thorsten Siess**, Wuerselen (DE); **Gerhard Doepper**, Wolperts (DE)

Correspondence Address:
FULWIDER PATTON LEE & UTECHT, LLP
200 OCEANGATE, SUITE 1550
LONG BEACH, CA 90802 (US)

(21) Appl. No.: **10/432,478**

(22) PCT Filed: **Nov. 16, 2001**

(86) PCT No.: **PCT/EP01/13262**

(30) **Foreign Application Priority Data**

Dec. 1, 2000 (DE)..... 100-59-714.9

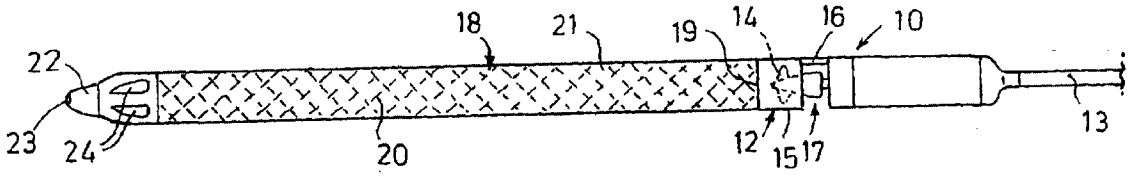
Publication Classification

(51) **Int. Cl.**[7] **A61N 1/362**

(52) **U.S. Cl.** **600/16**

(57) **ABSTRACT**

The pump **(10)** comprises a drive portion **(11)** and a pump portion **(12)** which have such a small diameter that they can be pushed through a blood vessel **(31)**. The pump portion **(12)** has a flexible cannula **(18)** connected thereto. In order to reduce the flow resistance of the cannula **(18)**, the cannula **(18)** can be dilated to a diameter that is larger than that of the drive portion **(11)** and the pump portion **(12)**, respectively. To be able to introduce the pump into the body by puncturing the blood vessel **(31)** according to the Seldinger technique, the cannula **(18)** is set into the constricted state in which it has a small diameter. In the blood vessel **(31)**, it is dilated so that it offers a small flow resistance to the blood to be pumped there.



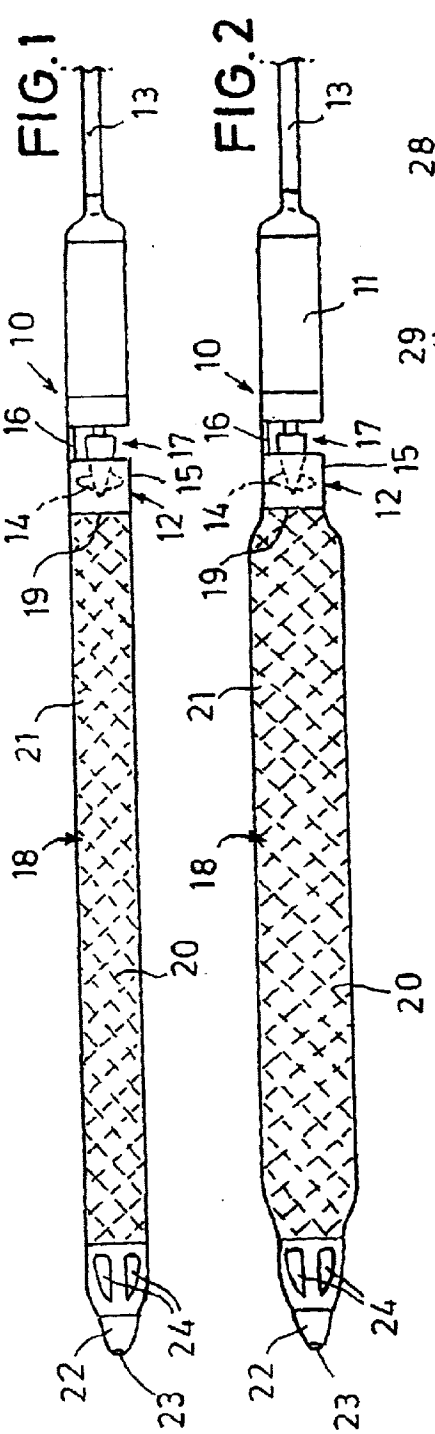


FIG.1
13
10
16
17
15
14
12
19
21
18
20
22
23
24

FIG.2
13
10
11
16
17
15
14
12
19
21
18
20
22
23
24

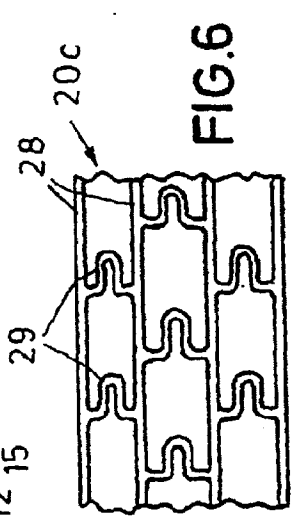


FIG.6
20c
28
29

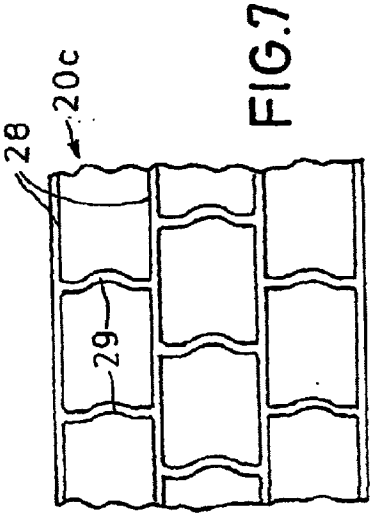


FIG.7
20c
28
29

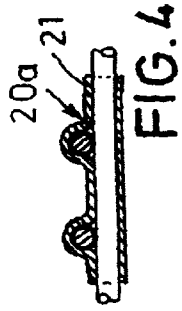


FIG.4
20a
21

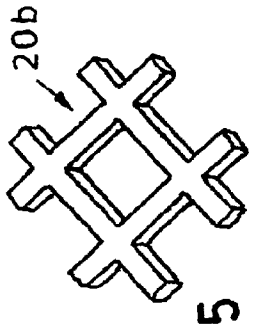


FIG.5
20b

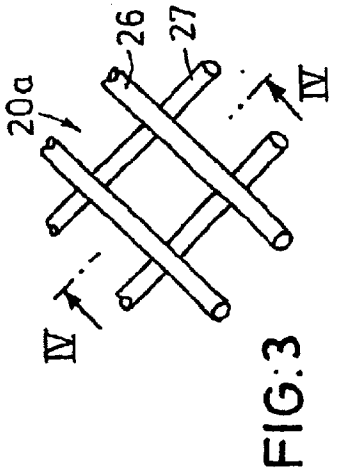


FIG.3
20a
26
27
IV
IV

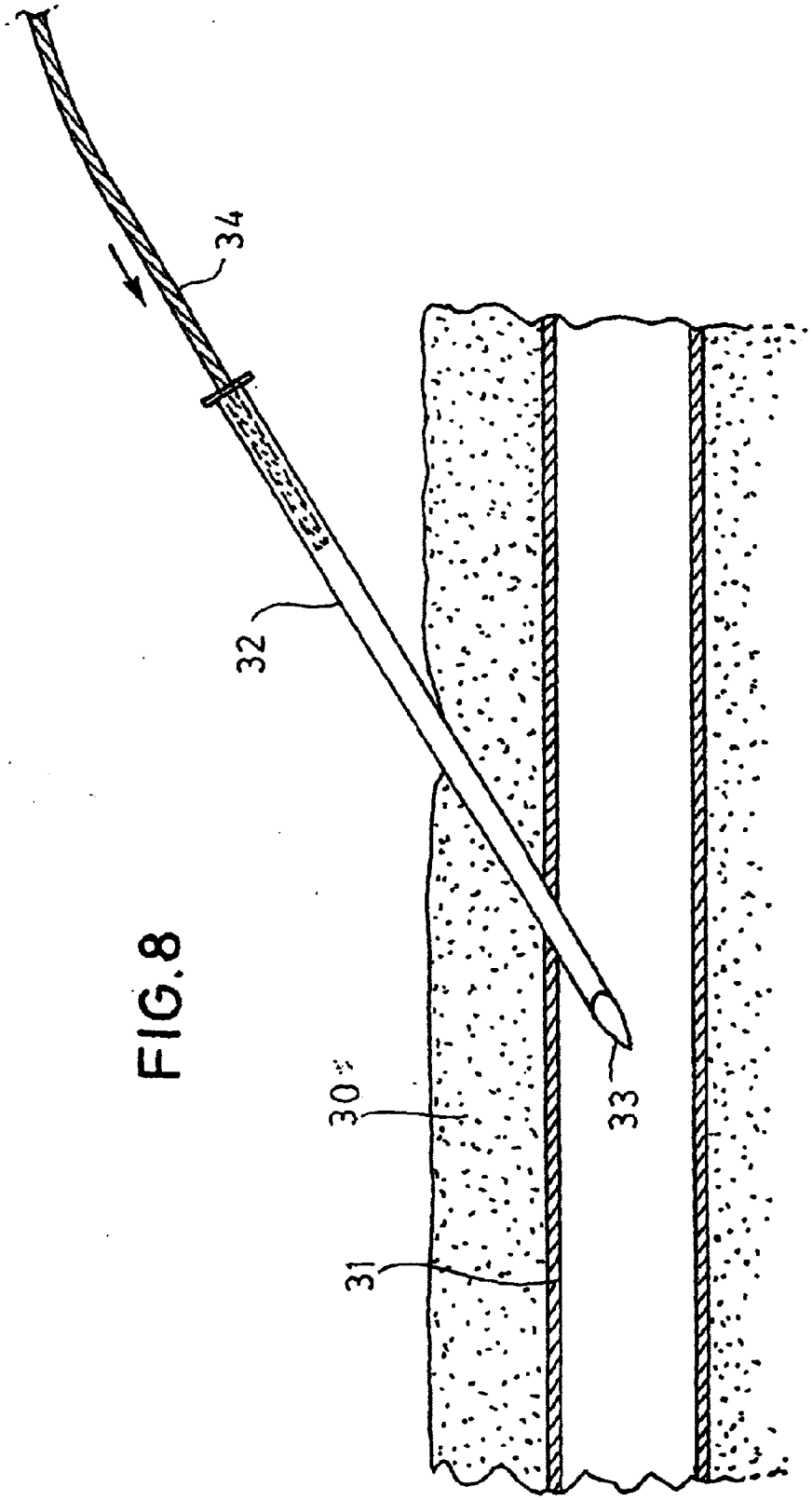


FIG.8

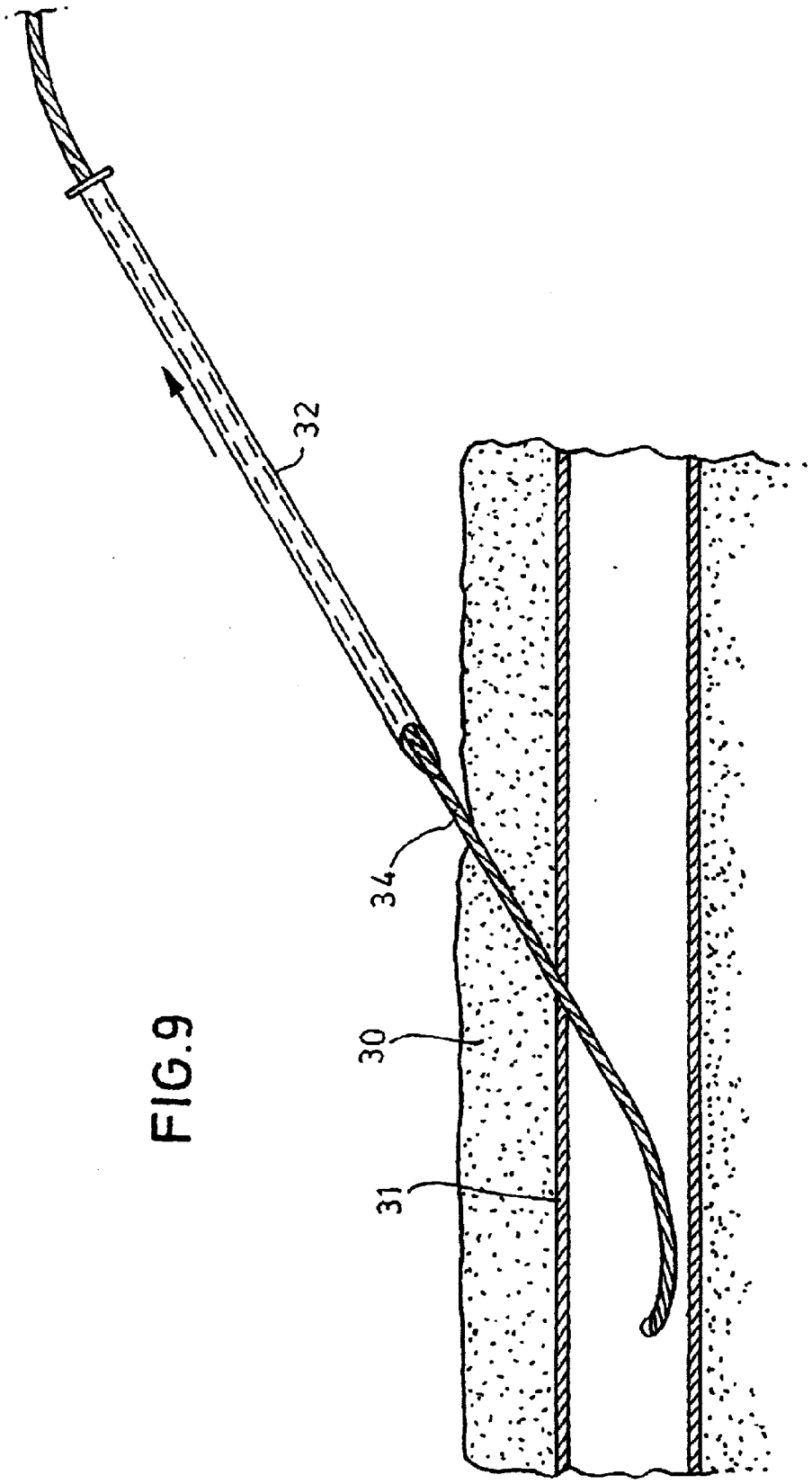


FIG.9

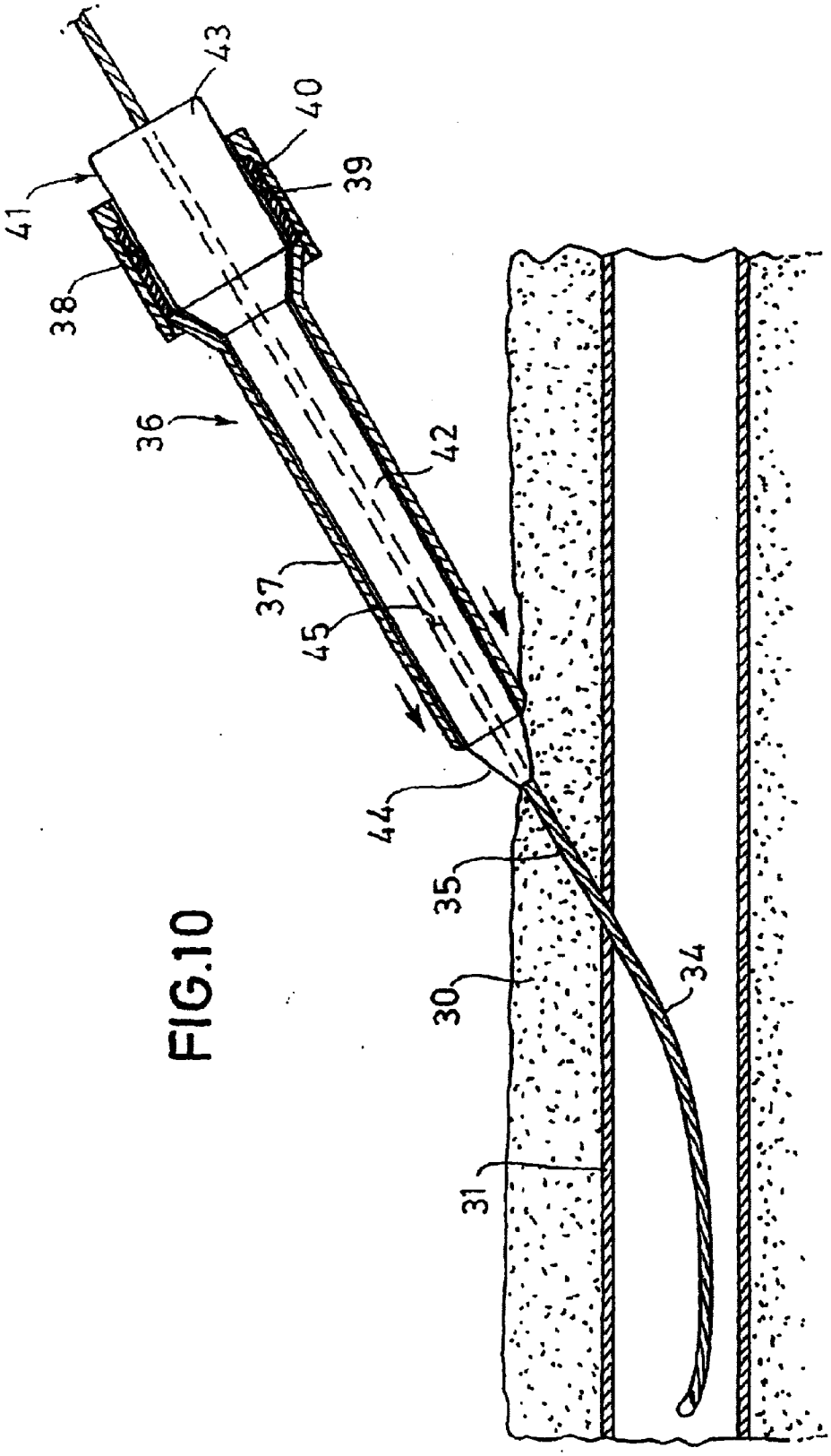


FIG.10

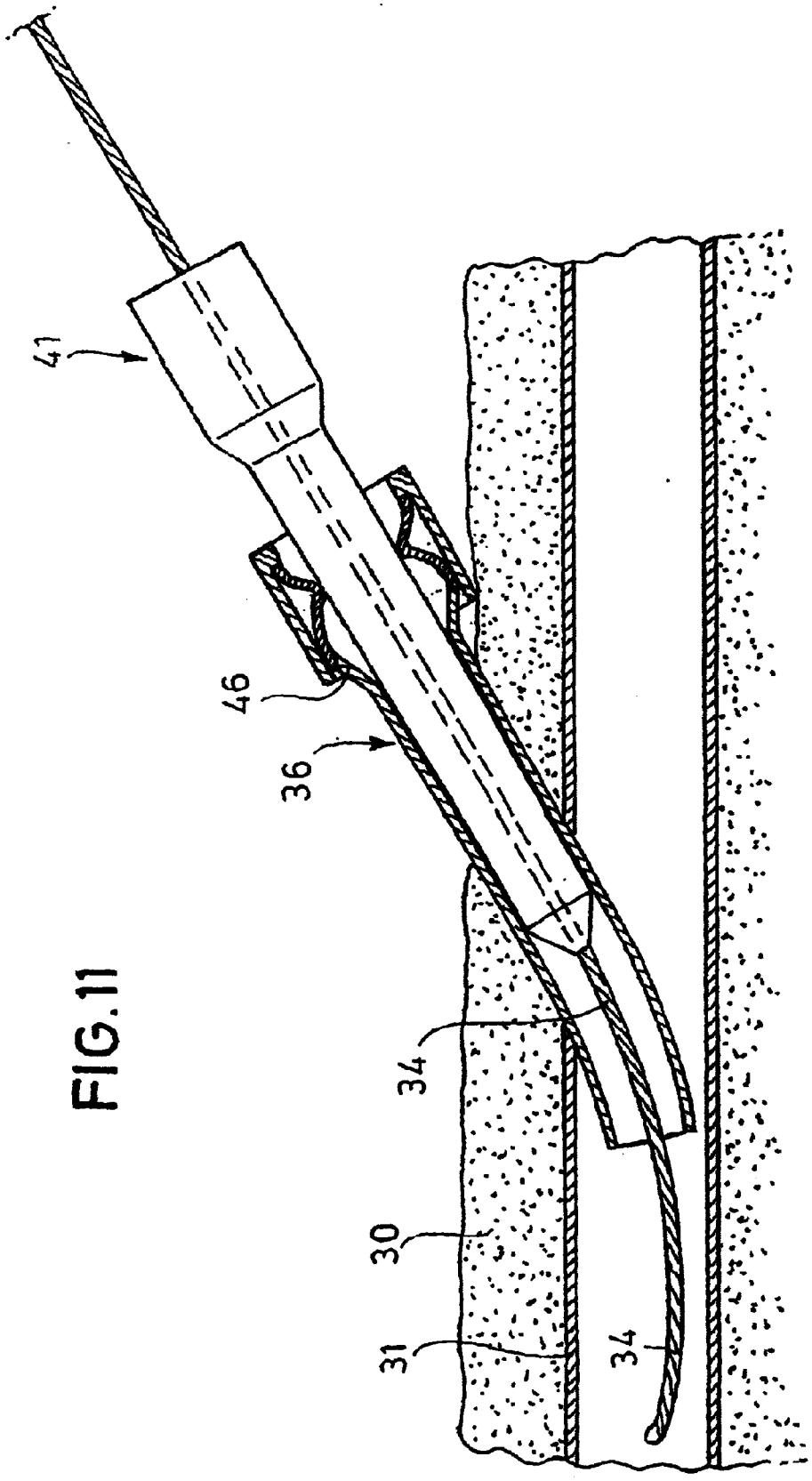


FIG.11

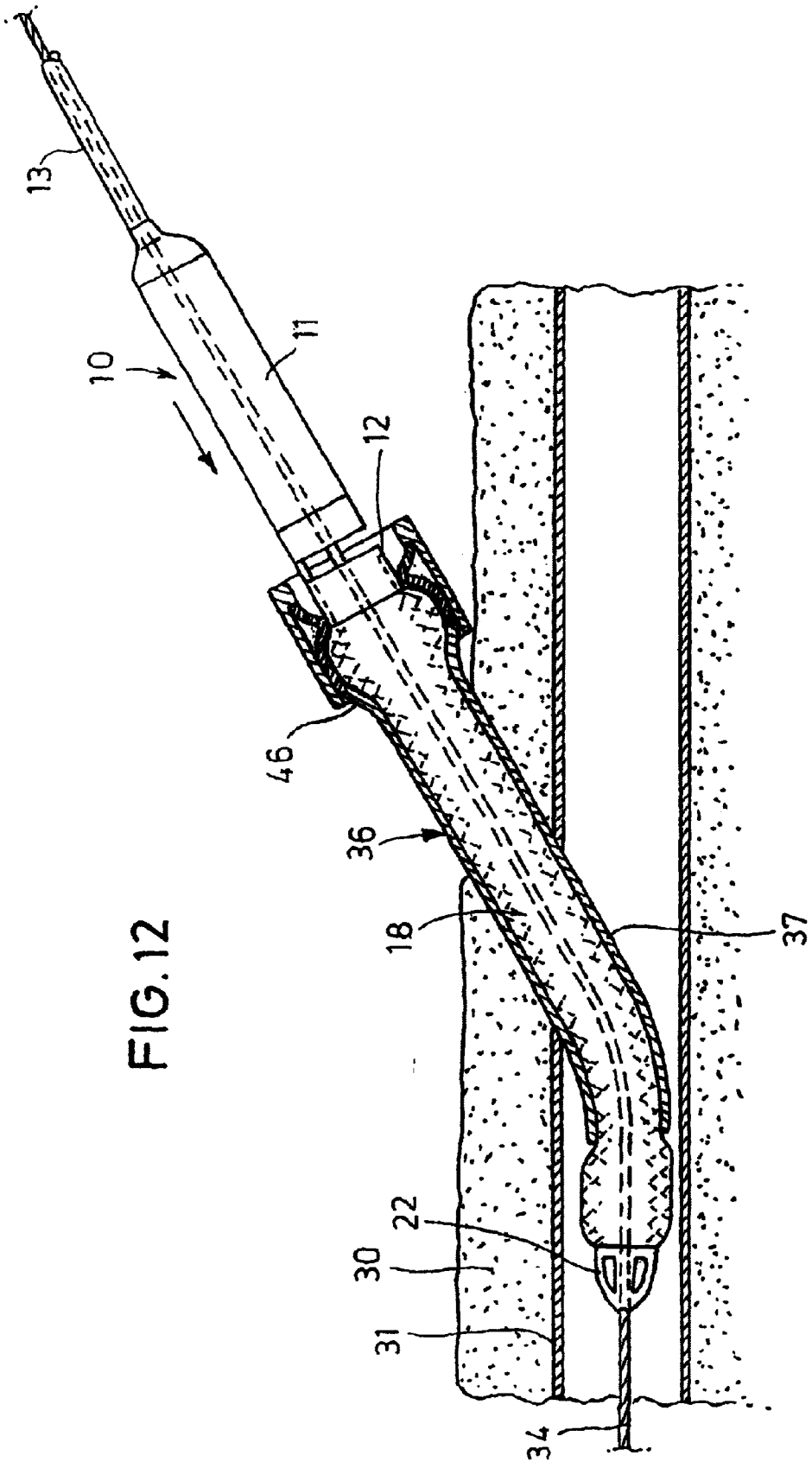


FIG. 12

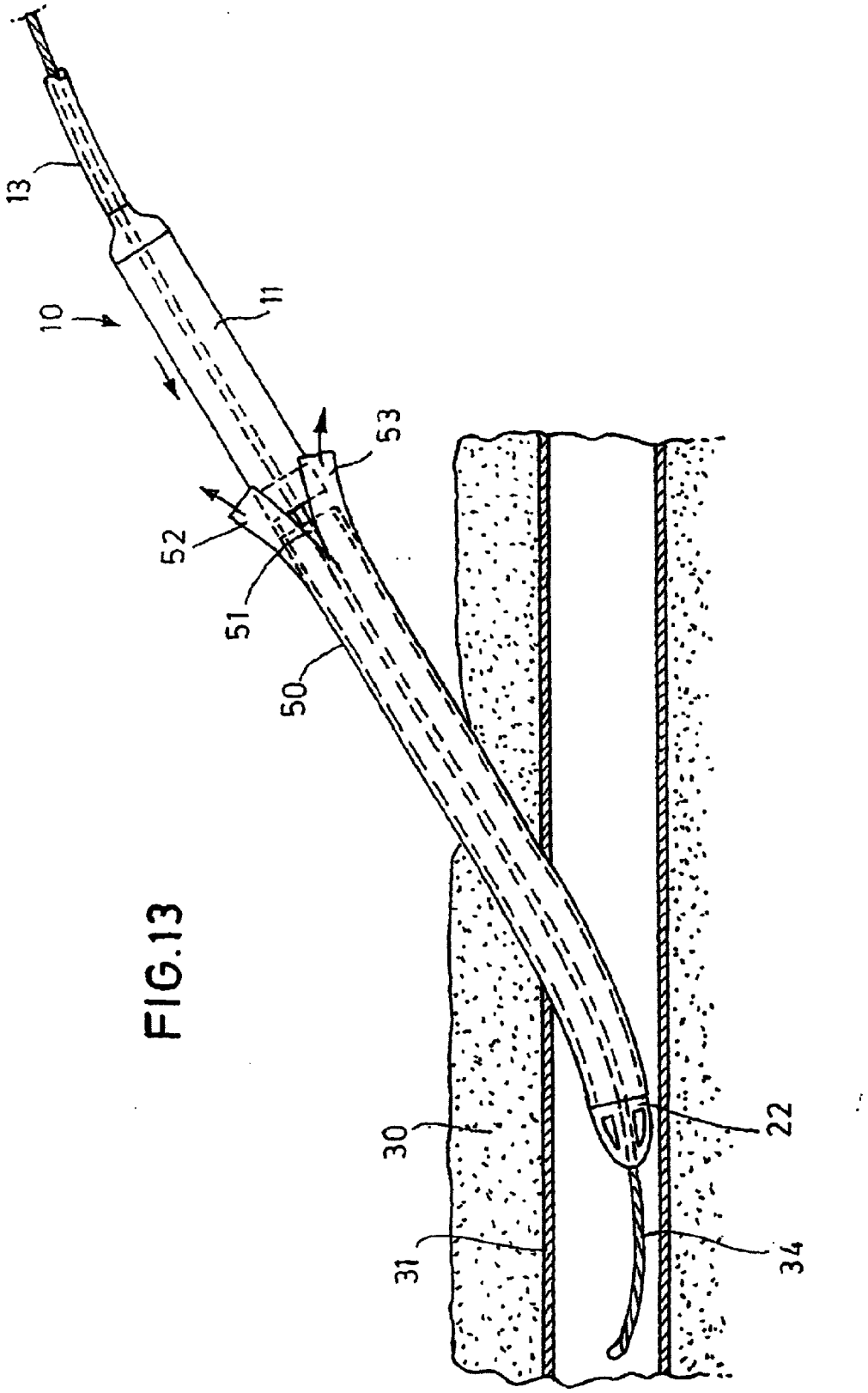


FIG.13

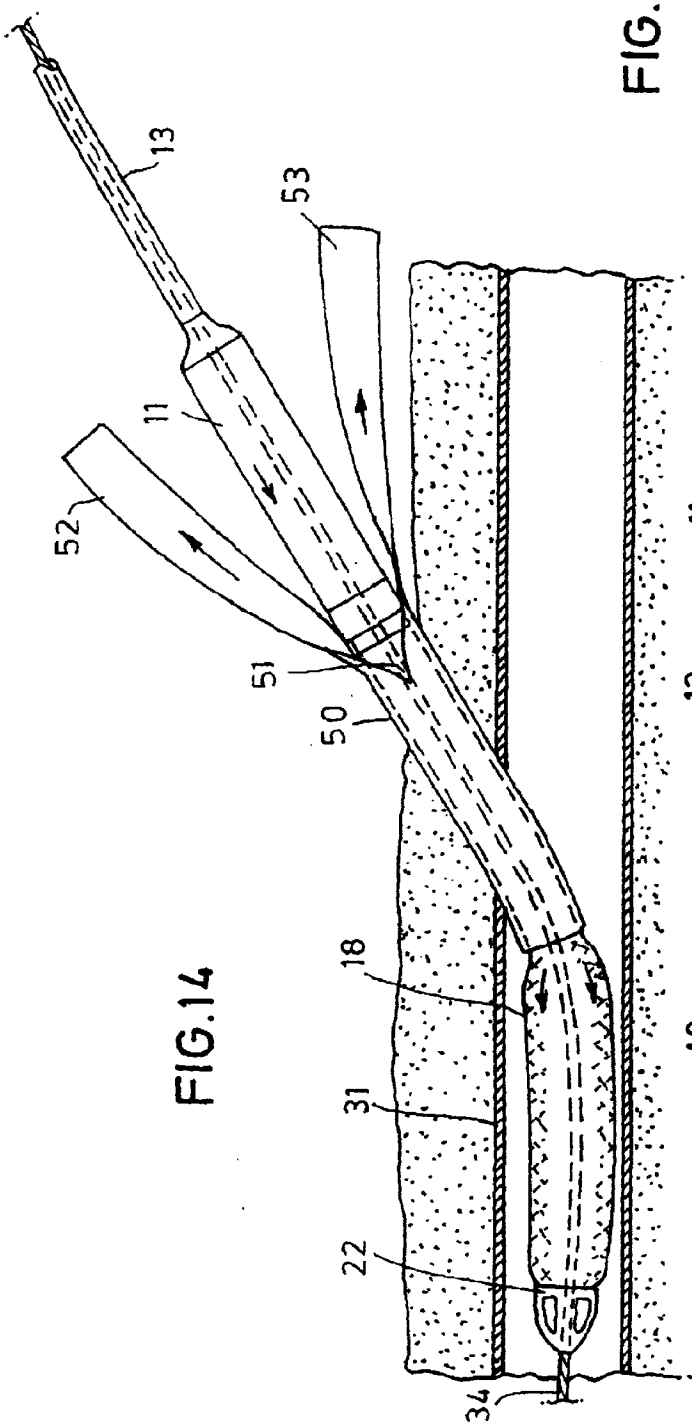


FIG.14

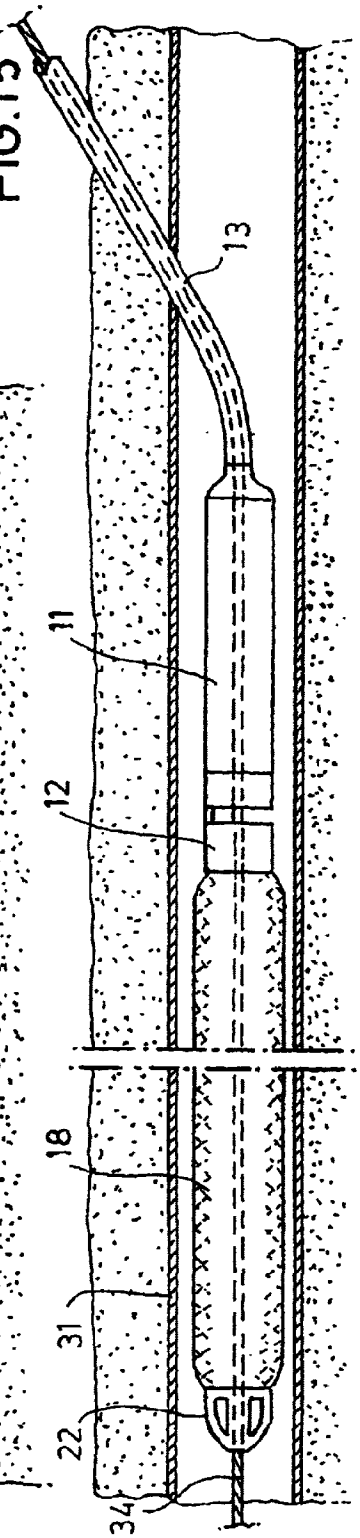


FIG.15

INTRAVASCULAR PUMP

[0001] The invention relates to an intravascular pump with a pump unit comprising a drive portion and a pump portion, and a flexible cannula extending from the pump portion.

[0002] An intravascular pump is a pump being adapted to be advanced through the blood vessel system of a patient in order to be introduced, e.g., into the heart. Such an intravascular pump is described in DE 198 21 307 C1. This pump comprises a drive portion with an electric motor and a pump portion driven by the electric motor. To this pump portion, an elongate cannula is connected and placed such that it passes through at least one cardiac valve. At the distal end of the pump, there are openings through which the pump can take in or eject. The pump unit is connected with a catheter including, among other things, the drive lines for the electric motor. The outer diameter of the blood pump is nowhere larger than 8 mm. For this reason, it is possible to advance the pump with the cannula in the vascular system of a human being. It is difficult, however, to introduce the pump into the body. To this end, an operation is typically necessary. It would be desirable to introduce a blood pump into the body by puncturing, by means of the Seldinger technique common with catheters, for example. Therefor, the diameter of the conventional intravascular pumps is too large. It is not possible to reduce the pump cross-section in the region of the cannula because the cannula would be too narrow for the required throughflow of 2 to 2.5 liters per minute. As a result of the high flow resistance of the cannula, a great portion of the pumping power produced by the pump would be lost.

[0003] It is the object of the present invention to provide an intravascular pump with a flexible cannula being adapted to be introduced into the body by the technique common with catheters and nevertheless permitting to pump at high flow rates.

[0004] This object is solved, according to the invention, with the features indicated in claim 1. Accordingly, the cannula consists of an expandable hose which is able to assume a state with a relatively small first diameter and a state with a relatively large second diameter. According to the invention, the cannula can be constricted such that it can be introduced into the body and the vascular system with the small first diameter. When it is located in the vascular system, it is expanded so that it then takes on the larger diameter required for the pump operation. The cannula is dimensionally stable but elastic. It is introduced into the body in a straight state, but when the pump is advanced into the heart, it preferably takes on a curved configuration corresponding to the radii of the vascular system. The cannula is not substantially compressible in longitudinal direction so that it can be advanced in a blood vessel without being substantially upset.

[0005] The applicant has succeeded in reducing the dimensions of the rigid pump unit such that the diameter is not larger than 4.0 mm. Therefore, the pump unit can be introduced into the body like a catheter by puncturing a blood vessel, e.g. a vein. Such a blood pump has an impeller rotating at high rotational speed of at least 30,000 revolutions per minute, typically of 60,000 revolutions per minute. The high pumping capacity associated therewith needs a cannula the outer diameter of which is larger than 4 mm. The pump according to the invention is introduced into the body with a constricted cannula, the cannula subsequently dilating when it is located in the blood vessel. Thus, a small puncturing spot is sufficient. A blood loss and the danger of infection always associated with operations are avoided or reduced. In the expanded state, the diameter of the cannula is larger than that of the drive portion.

[0006] The cannula may comprise a material with shape memory. Such a material, e.g., nitinol, forms the frame of a jacket otherwise consisting of plastic and forming the cannula. In its constricted state, the cannula is "frozen" at room temperature, i.e., the nitinol wire is in the plastic range below the transition temperature of glass. If it is heated to body temperature as a result of the body heat, it takes on the expanded state with an enlarged diameter in the superelastic state. Thus, it is possible to expand the outer diameter of the cannula from about 4 mm to about 5.5 mm or more.

[0007] The cannula may also consist of an elastic material biased into the expanded state, which is mechanically compressed when being introduced into the body and expands in the interior of the blood vessel.

[0008] According to a preferred embodiment of the invention, the cannula is provided with a rigid head piece. The head piece can be used as a dilator. It is provided with an opening for the passage of a guide wire and continuously expands in proximal direction. Such a cannula can be pushed upon a guide wire leading percutaneously into a blood vessel and then acts as a dilator dilating the channel of body tissue containing the guide wire and allows the insertion of the entire pump through the dilated opening.

[0009] Hereinafter, embodiments of the invention are explained in detail with respect to the drawings.

[0010] In the Figures:

[0011] **FIG. 1** is a side view of the intravascular pump in the constricted state,

[0012] **FIG. 2** is a side view of the pump in the expanded state,

[0013] **FIG. 3** is an illustration of the wire structure of the deformable cannula,

[0014] **FIG. 4** is a sectional view along the line IV-IV of **FIG. 3**, the wires, however, being enclosed by a jacket or a skin,

[0015] **FIG. 5** shows another embodiment of a lattice of the cannula, the outer jacket, however, not being illustrated,

[0016] **FIG. 6** shows a further embodiment of a supporting structure of the cannula in the constricted state,

[0017] **FIG. 7** shows the supporting structure according to **FIG. 6** in the expanded state,

[0018] **FIG. 8** shows the percutaneous puncturing of a blood vessel and the introduction of a guide wire,

[0019] **FIG. 9** shows the withdrawal of the steel cannula used for the puncturing,

[0020] **FIG. 10** shows the introduction of a sluice into the blood vessel by using a dilator,

[0021] **FIG. 11** shows the withdrawal of the dilator,

[0022] **FIG. 12** shows the insertion of the pump through the sluice into the vessel, the cannula of the pump expanding in the interior of the blood vessel,

[0023] **FIG. 13** shows an embodiment in which the cannula is provided with a tearable coating which keeps it in the constricted state and can be peeled off,

[0024] **FIG. 14** shows the withdrawal of the coating from the cannula, and

[0025] **FIG. 15** shows the pump advancing in the blood vessel.

[0026] The pump illustrated in **FIGS. 1 and 2** comprises a pump unit **10** consisting of a drive portion **11** and a pump portion **12**. The drive portion **11** has a cylindrical configuration with an outer diameter of about 4 mm. Its proximal end is connected with a catheter **13** which includes a catheter lumen extending throughout and through which the wires for the provision of the electric motor included in the drive portion **11** extend as well. The drive portion **11** drives a shaft on which an impeller **14** located in the pump portion **12** is seated. The impeller **14** rotates in the interior of a ring **15** which forms the pump housing. The pump portion **12** is arranged at an axial distance from the drive portion **11** and connected therewith via longitudinally extending webs **16**. The webs **16** bridge the opening **17** forming the outlet or the inlet of the pump, depending on the rotational direction and configuration of the impeller **14**. When the opening **17** forms the inlet, the impeller **14** supplies the blood **14** in axial direction into the cannula **18** which is connected to the axial opening **19** forming the outlet. The blood flow can also occur vice versa.

[0027] The cannula **18** forms a pump hose having a length of about 50 to 60 mm. It is dimensionally stable but elastic. The cannula **18** includes a supporting structure **20** and a closed jacket **21** covering the supporting structure. At the distal end of the cannula **18**, there is a rigid head piece **22** expanding from the distal end to the proximal end and comprising an opening **23** for the passage of a guide wire. There are further openings **24** for the passage of the blood to be pumped at the head piece **22**.

[0028] In the state illustrated in **FIG. 1**, the cannula **18** has a small outer diameter which about corresponds to the outer diameter of the pump unit **10**, which is 4 mm in the present case. In this state, the cannula **18** is flexible so that it can be bent to be introduced into the vascular system.

[0029] In **FIG. 2**, the pump **10** is illustrated with expanded cannula **18**. Now, the outer diameter of the cannula **18** amounts to about 5.4 mm. Compared with **FIG. 1**, the length of the cannula is unchanged. This state is the operational state of the cannula it takes when the pump unit **10** operates.

[0030] **FIGS. 3 and 4** illustrate an embodiment of the supporting structure **20***a* of the cannula **18**. The supporting structure **20***a* consists of intersecting elastic wires **26** and **27** forming a parallelogram structure. The wires **26**, **27** are wound helically and interconnected by the jacket **21** consisting of plastic. At their intersections, they have such an orientation that the cannula **18** tends to assume the expanded state. On the other hand, the cannula can be brought into the constricted state by compression.

[0031] **FIG. 5** shows a similar supporting structure **20***b* consisting of a lattice the bars of which also extend diagonally and form a parallelogram structure. The lattice bars lie in the same plane. The lattice can be made of a tube by laser cutting, for example. It consists of a metal alloy with shape memory, e.g., of nitinol. At room temperature, the lattice is plastically "frozen" in the constricted state and can be superelastically expanded by heating to body temperature.

[0032] **FIGS. 6 and 7** show a further embodiment of a supporting structure **20***c* with shape memory. This supporting structure includes longitudinally extending straight webs **28** connected by transversely extending loop webs **29**. The supporting structure forms a tube. The loop webs **29** have a shape memory. They are frozen in the highly bent state shown in **FIG. 6** and can be dilated by heat to the stretched state illustrated in **FIG. 7**. A jacket consisting of plastic combined with the supporting structure **20***c* is provided here as well.

[0033] As an alternative to a material with shape memory, an elastic spring steel can be used as well which, when formed correspondingly, is only deformed in the elastic range and thus passes to the expanded state after it has been compressed.

[0034] FIGS. **8** to **12** show a first technique of introducing the pump into the blood vessel system. According to **FIG. 8, a** blood vessel **31** is first punctured through the skin **30** by means of a steel cannula **32** with a cutting tip **33**. Through the steel cannula **32**, a guide wire **34** is introduced and then advanced in the blood vessel **31**, as is shown in **FIG. 9**. Thereafter, the steel cannula is withdrawn.

[0035] According to **FIG. 10, a** sluice **36** is introduced into the puncturing channel **35** through which the guide wire **34** passes. The sluice **36** consists of a relatively rigid tube **37** the inner diameter of which is somewhat larger than 4 mm and a hemostatic valve **38** arranged at the proximal end of the tube **37**. The hemostatic valve **38** includes an elastomeric annular member **39** which is axially compressed by twisting a screw cap **40** and simultaneously evades radially inward.

[0036] In the sluice **36**, a dilator **41** is seated which comprises a shank **42** filling up the tube **37** and a head **43** seated in the valve **38** at the rear end. The annular member **39** of the valve is pressed against the head **43** when the screw cap **40** is tensioned so that no blood can escape from the sluice. The dilator **41** comprises a conical tip **44** protruding from the tube **37**. A channel **45** through which the guide wire **34** can be pushed extends through the length of the dilator. The dilator **41** serves to dilate the puncturing channel **35** and to introduce the tip of the sluice **36** into the blood vessel **31**.

[0037] **FIG. 11** shows the withdrawal of the dilator **41** from the sluice **36**, so that the latter is now ready for the introduction of the pump **10**.

[0038] According to **FIG. 12**, the pump **10** is introduced into the sluice **36** such that the head **22** is inserted into the proximal end of the sluice first. The head **22** has the same maximum outer diameter as the pump unit **10**. Then, the remaining portion of the cannula **18** follows, which is radially compressed by the tapering portion **46** at the rear sluice end and is pushed through the tube **37** in the compressed state. In the blood vessel, the cannula **18** emerges from the sluice **36** and then expands again as a result of its elastic bias. Thus, the entire pump with cannula **18** and pump unit **10** is inserted into the blood vessel over the guide wire **34**. Thereafter, the sluice **36** and the guide wire **34** are removed.

[0039] FIGS. **13** to **15** show another manner of introducing the pump **10** into the blood vessel **31**. Here, the cannula is held in the constricted state by a tubular coating **50**. The coating **50** consists of a thin-walled hose comprising two longitudinally extending fissures **51** at the rear end which allow to rip up the hose into two separate sheets **52**, **53**. The coating **50** consists of a sheet the molecular structure of which is directed in longitudinal direction of the hose so that each fissure continues in longitudinal direction when the sheets **52**, **53** are torn apart.

[0040] When the pump is introduced over the guide wire **34**, the head **22** serves as dilator dilating the puncturing channel upon advancing the pump **10**. Neither a sluice nor a separate dilator is required therefor. When the state illustrated in **FIG. 13** is reached, the coating **50** is peeled off in proximal direction, while the pump **10** is further advanced over the guide wire **34**. When the coating **50** is withdrawn, it is split. In this manner, the entire pump is introduced into the blood vessel while the coating **50** is withdrawn simultaneously. In the region of the cannula, the outer diameter of the coating **50** amounts to about 3.0 mm, so that, when the hose is withdrawn, the fissures automatically propagate over the pump portion which is approximately 1 mm larger.

[0041] Typically, the yield of the pump in the state illustrated in **FIG. 15** amounts to 2.0 to 2.5 liters per minute.

[0042] If the cannula consists of an elastically dilatable material, i.e., no material with shape memory, it preferably includes a spring steel wire that can be helically wound. By welding individual wires or due to a plastic jacket with varying thickness, the rigidity of the cannula may vary over the cannula length. Preferably, the distal front end of the cannula is soft and the hardness of the cannula increases in rearward direction. The soft cannula tip allows to place the cannula atraumatically in the aortic valve.

1. An intravascular pump comprising a drive portion **(11)**, a pump portion **(12)** connected therewith and a flexible cannula **(18)** projecting from the pump portion **(12)**, characterized in that

the cannula **(18)** consists of an expandable hose being adapted to assume a state with a relatively small first diameter and a state with a relatively large second diameter.

2. The pump according to claim 1, characterized in that the cannula **(18)** comprises a material with shape memory which assumes the state with the small diameter at a low temperature and assumes the state with the larger diameter at a higher temperature.

3. The pump according to claim 1, characterized in that the cannula is contained in a tubular coating **(50)** in a constricted state and, upon removal of the coating **(50)**, assumes an expanded state while dilating elastically.

4. The pump according to one of claims 1 to 3, characterized in that a tubular sluice **(36)** is provided through which the cannula **(18)** is adapted to be pushed in the constricted state.

5. The pump according to one of claims 1 to 4, characterized in that the cannula **(18)** comprises a rigid head piece **(22)**.

6. The pump according to claim 5, characterized in that the head piece **(22)** comprises an opening **(23)** for the passage of a guide wire **(34)**.

7. The pump according to one of claims 1 to 6, characterized in that the drive portion **(11)** and the pump portion **(12)** comprise a longitudinally extending channel for a guide wire **(34)**.

8. The pump according to claim 4, characterized in that the sluice **(36)** comprises a sealing **(38)** acting against the cannula **(18)**.

9. The pump according to claim 3, characterized in that the coating **(50)** comprises longitudinally extending fissures **(51)** permitting a tear into two separate sheets **(52, 53)**.

10. The pump according to claim 1, characterized in that the cannula is radially spring-elastic.

11. The pump according to claim 10, characterized in that the rigidity of the cannula increases from the cannula tip to the rear.

* * * * *